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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/768,826 | 01/25/2001 | Yanggu Shi | PF512P1 | 2604 |

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| EXAMINER | |
|---|---|
| MITRA, RITA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | 7 |

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/768,826 | SHI ET AL. | |
| | Examiner | Art Unit | |
| | Rita Mitra | 1653 | |

*-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --*

**Period f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *24-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Status of the Claims*

Applicants' preliminary amendment filed on July 12, 2002 (paper #6) is acknowledged. Amendment to specification at page 1 has been noted. Claims 1-23 have been canceled. New claims 24-63 have been added. Therefore, claims 24-63 are currently pending and are under examination.

### *Priority*

Applicants' claim for domestic priority under 35 U.S.C. 119 (e) is acknowledged. However, the parent application 60/148759 at page 1 of the specification fails to provide the support to SEQ ID NO: 47 of instant application. Neither the PCT/US00/22350 filed on August 15, 2000 provides the support. Therefore, in the current prosecution the filing date, January 25, 2001 is considered as a priority date.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 24-63 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polypeptides are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polypeptides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polypeptides such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed. The reasons are as follows:

The specification, on page 69 (Gene18) and page 73 (Table 1) describes clone HBIMF63 (ATCC NO: PTA-536) to which the instant invention relates. The specification asserts (page 69) that translation product of this gene shares sequence homology with ligand binding protein which is thought to be important in cell-to-cell communication and signal transduction. Further, the translation product of this gene also shares sequence homology with lymphocytoma proliferation activating peptide (LPAP). Based on the specification (pages 69-72); and Examples 5-8, no biological activity has been set forth for the polypeptide of clone HBIMF63 nor any use for the polypeptide itself has been provided. Only speculative biological activities have been provided on page 130-147, 167-275 of the specification. In examples 1-58, it appears that these experiments have not been performed because the examples are not written in the past tense. Therefore, they appear to be prophetic examples ((MPEP 608.01 (p)). For example, the use of the protein for further research is described here (page 167-170). This use is not a patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed proteins. This situation requires carrying out future research to identify or reasonably confirm a "real world" context of use and therefore does not define specific and substantial utility.

Other activities that the protein may exhibit are listed throughout page 275-277 of the specification. However, these activities are speculative. In summary, the proteins claimed do not have a credible, specific or well-established or even demonstrable utility and therefore lacks utility under 35 U.S.C. 101.

Claims 24, 25, 26, 35, 38, 42, 45, 49, 52, 56, 57, 60 and 61, are drawn to a protein comprising a sequence of SEQ ID 47 and fragments thereof. The specification does not describe the functional properties of the entire protein or its fragments, and the structural information is limited. While the specification enumerates several known assays for biological activity (p. 316-329, Examples 13-20), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed fragments for which no known activity is explicitly disclosed nor demonstrated.

Claims 30, 31, 33, 49, 54, 60, 61, and 62 are drawn to proteins or a fragment encoded by the cDNA of clone HBIMF63. It is not clear from the description of the clone (specification

page 69-72, 96-100) about the protein structure, aside from its amino acid sequence, and/or its function. As discussed above, based on the specification (page 69-72, 96-100) it is unclear what activity the claimed proteins or protein fragments possess or how a person having skill in the art would have used the claimed proteins.

Claims 27, 33, 39, 47, 54, 58, and 62 are drawn to a protein of claims 24, 32, 35, 46, 53, 56 and 60 respectively, which comprises a heterologous polypeptide sequence. It is not clear from the description on page 145-147 and page 306 (Example 9) what is the heterologous protein's structure, and /or its function.

Claims 28, 34, 40, 48, 55, 59 and 63 are directed to a composition comprising the protein of claims 24, 32, 35, 46, 53, 56, 60 respectively and a pharmaceutically acceptable carrier. The speculative composition and their administration and dosage are listed in the specification (pages 331-356, Example 23), however, when the proteins claimed lack a credible, specific or well established utility, the composition of those proteins would also lack utility under 35 U.S.C. 101. Applicants assert on page 331 that the composition would be useful in the treatment of conditions associated with disease. Examples of many therapeutic methods have been described in pages 331-356 but the specification does not indicate explicitly the correlation of the role of the protein or the composition containing the protein to a specific disease treatment.

Claims 29, 32, 41, 46 and 53 are drawn to a protein produced by the method comprising expressing the protein by a cell and recovering the protein. Specification on page 147-159 describes the vectors and host cells but does not indicate the function of the expressed protein.

Claims 35, 42 and 49 and dependent claims 36, 37, 43, 44, 50, 51 thereto are drawn to an isolated first polypeptide at least 90% identical to a second polypeptide comprising amino acid sequence of SEQ ID NO: 47 and fragments thereof, wherein said first polypeptide is used to generate or select an antibody that specifically binds said second polypeptide. The specification at page 99, lines 2-10 while defining "functional activity" of a polypeptide, indicates that such functional activities include biological activity, antigenicity, immunogenicity etc. etc. However, specification fails to describe or demonstrate any such activity of the claimed protein that can be correlated with the antigenicity or immunogenicity activity, moreover, no such activity of the

claimed protein has been demonstrated using Western Blot and ELISA as claimed in claims 36, 37, 43, 44, 50, 51.

In the instant case, the failure of the specification to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the protein set forth in SEQ ID NO: 47 other than the fact that the protein shares homology with ligand binding protein (p. 69). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 47 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-63 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claims 30-34, 49, 53, 54 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 30-34, 49, 53, 54 and 60-62 are rejected because these claims recite necessity of a deposited clone, ATCC PTA-536, and do not meet fully with the deposit requirements. The specification at page 4 indicates that the deposit has been made under the Budapest Treaty, and the composite deposit of several clones (including clone HBIMF63) has been deposited with ATCC and were given the Accession number ATCC PTA-536. However, Applicants fail to provide a copy of the deposit receipt. Submission of a copy of the receipt would overcome this rejection.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 24, 25, 29-32, 35- 46, 49-53, 56, 57, 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24, 25, 35, 38, 42, 45, 49, 52, 56, 57, 60, 61 are indefinite since it is unclear by absence in the claim recitation whether or not the polypeptide fragments are active, or what that activity may be.

In claims 29, 32, 41, 46 and 53 it is unclear as to whether or not the process claimed would have resulted in a protein that has the same physical, chemical, and biological properties and functions as the protein of SEQ ID NO: 47 and the proteins encoded by the cDNA insert of clone HBIMF63 (ATCC NO: PTA-536) since the present application does not indicate a function for the protein or the fragments thereof.

Claim 30 and the dependent claim 31 are indefinite because it requires the protein to be the complete polypeptide but yet at the same time is missing the N-terminal methionine.

Claims 35, 42 and 49 are indefinite because of the use of the term "capable." It is not clear whether the first polypeptide is actually needed to generate or select an antibody, or merely have the capability to do so. The word "capable" associates with the latent function only. Amending the claim by deleting the term "capable" would obviate the rejection. Claims 36-41, 43-46 and 50-53 are included in the rejection because these claims are dependent on rejected claim and do not correct the deficiency of the claim from which they depend.

***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-26, 30, 31 are rejected under 35 USC 102 (b) as being anticipated by Dear et al. (The EMBO Journal, vol 10, NO. 10, pp. 2813-2819, 1991). Dear et al. teach three novel genes exclusively expressed in the olfactory mucosa, the predicted proteins of which are homologous to a variety of ligand-binding proteins (see page 2813 abstract and col 2, second paragraph; page 2816, Fig. 3), having 67.9% sequence identity to amino acid residues 24-105 of SEQ ID NO: 47 (see alignment result 1, PIR_73 database, Accession NO: S17449, January 13, 1995). This sequence is considered for an analog of SEQ ID NO: 47 and also for encoded by cDNA insert of clone HBIMF63, thus anticipating claim 24.

As to claims 25, 30, 31 Dear et al. teach three novel genes exclusively expressed in the olfactory mucosa, the predicted proteins of which are homologous to a variety of ligand-binding proteins (see page 2813 abstract and col 2, second paragraph; page 2816, Fig. 3), having 64.2% sequence identity to amino acid residues 2-105 of SEQ ID NO: 47 (see alignment result 1, PIR_73 database, Accession NO: S17449, January 13, 1995). This sequence is considered for an analog of SEQ ID NO: 47 and also for encoded by cDNA insert of clone HBIMF63 (25). Dear et al.'s protein is also without N-terminal methionine, thus anticipating claims 30 and 31.

As to claim 26 Dear et al. teach three novel genes exclusively expressed in the olfactory mucosa, the predicted proteins of which are homologous to a variety of ligand-binding proteins (see page 2813 abstract and col 2, second paragraph; page 2816, Fig. 3), having 64.5% sequence identity to SEQ ID NO: 47 (see alignment result 1, PIR_73 database, Accession NO: S17449, January 13, 1995). This sequence is considered for an analog of SEQ ID NO: 47 and also for encoded by cDNA insert of clone HBIMF63, thus anticipating claim 26.

***Conclusion***

No claims are allowed.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
September 28, 2003

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